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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/755,018 | 01/09/2004 | Bianca A. Thomae | 07039-440001 | 8952 |

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EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT PAPER NUMBER

1652

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|--------------------------------------|--|
| Office Action Summary | Application No. 10/755,018 | Applicant(s) THOMAE ET AL. | |
| | Examiner Kagnew H. Gebreyesus | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,17-33 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) 3-7,9,10,13-15 and 17-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 11 and 12 is/are allowed.
- 6) ☒ Claim(s) 1,8,11,12 and 38 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/2/06 & 5/16/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I comprising claims 1-12 and 16 dated July 13, 2006 is acknowledged. Claims 2, 16, 34-37 are cancelled. New claims 38-41 are added. Claims 13-15 and 17-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected groups, there being no allowable or linking claims and claims 3-7, 9 and 10 are withdrawn as drawn to non-elected species. Claims 1, 8, 11, 12, 38-41 with further election of a variant at position 298 of SEQ ID NO: 6 are present for examination. Applicants erroneously included cancelled claim 2 in the elected group.

Reply to traversal:

Applicants traverse the election requirement and argue:

"The MPEP 803.04 recites that in most cases up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." (Emphasis added.) Thus, it is reasonable to assume that more than one PNMT sequence recited in the present claims would be susceptible to examination in the instant examination. For example, Applicants respectfully suggest that with respect to the amended claims, the Office could search two, five, or ten different nucleotide sequences, each containing 19 contiguous nucleotides from SEQ ID NO: 1 or SEQ ID NO: 6, with each sequence having one of the recited variant positions at position 10. Applicants submit that there would be no undue burden on the Office to conduct such a search. As such, restriction to a single variant nucleic acid sequence is not warranted. To require a restriction to a single variant sequence for examination purposes imposes greater hardship on Applicants than it would on the Office.

Applicants further argue:

"...that this argument goes to the perceived burden of search and is not to be construed as an admission that claims reciting particular variant PNMT sequences are not patentably distinct from one another".

Applicants traversal is not found persuasive for the following reasons: Applicant is reminded that the MPEP recites up to 10 distinct nucleotide sequences not at least 10 nucleotide

Art Unit: 1652

sequences, and applicants assert that the Office could search two, five, or ten different nucleotide sequences, each containing 19 contiguous nucleotides from SEQ ID NO: 1 or SEQ ID NO: 6, with each sequence having one of the recited variant positions at position 10 without undue burden. However each of the 19 contiguous nucleotides derived from SEQ ID NO: 1 or SEQ ID NO: 6 are structurally distinct because they span different regions of SEQ ID NO: 1 or SEQ ID NO: 6. Thus each of the sequences must be searched in both non-patent and patented literatures and sequence databases given that each sequence represents a PNMT polynucleotide variant distinct from the other.

For the reason given above the requirement for restriction is maintained and is still deemed proper and is therefore made FINAL.

A search and examination will be extended to additional species if the elected species is found to be allowable.

Priority

Priority is acknowledged for this application which claims the benefit from U.S. Provisional Application Serial No. 60/438,930, filed January 9, 2003.

Information Disclosure Statement

The information disclosure statement filed on May 16, 2005 and February 02, 2006 for which a copy of the patent publication has been submitted in this application will be reviewed in full.

Oath/Declaration

The oath or declaration submitted on May 13, 2004 has been reviewed and is in compliance with 37 CFR 1.63.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Fodor et al. (US PG-PUBS 2001/0053519).

Fodor et al. teach a complete set of “n-mer” which represents a set of single stranded polynucleotides of “n” number of nucleotides wherein the set represents every possible combination of “n” nucleotides. Thus the complete set of 10-mer having a sequence 10 nucleotides anticipates each variant disclosed in 1, 8 and 38 including the variant at position 298.

Furthermore search was extended to nucleotide variants at other positions. The following rejection applies to positions 1509 and 1303 in SEQ ID NO: 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1652

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 38-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Comings et al (US 6,660,476 B2). Coming et al teach a polynucleotide encoding a phenylethanolamine N-methyltransferase comprising a G to A variant at positions -182 and a G to A variant at position -387. These residues correspond to nucleotide residues at positions 1303 and at position 1509 in the sequence of SEQ ID NO: 1 disclosed in applicants invention. On page 7, column 1, line 21, Coming et al disclose molecular cloning of the PNMT alleles, and sequencing the alleles thus anticipating claims 38, 39 and 40. In addition page 8 line 42-52 of Coming et al disclose the use of allele specific probes of about 30 nucleotides derived from PNMT to be used for the detection of variants of PNMT sequences. The cloning of amplified sequences is taught for example on page 10 line 9-15 thus anticipating claims 41. Therefore the disclosure by Coming et al anticipates claims 1, 38-41 in applicant's disclosure.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by a polynucleotide sequence submitted GenBank with the accession No. AC079199.9 submitted (23-AUG-2000) corresponding to a locus on Homo sapiens chromosome 17, clone RP11-94L15 comprising a sequence encoding a human phenylethanolamin N-methyltransferase and which shows a G to T mutation at position 12329, a position that corresponds to position 1102 of SEQ ID NO: 1 claimed in the instant application (see claim 1(d)). Given claim 1(d) comprises an embodiment drawn to a polynucleotide sequence with at least 10 contiguous nucleotides of SEQ ID NO: 1 wherein said sequence includes nucleotide position 1102 with the proviso that the nucleotide at this position is a thymine (T), it is anticipated by the polynucleotide sequence of GenBank NO. AC079199.9 which also includes a G to T mutation at a position corresponding to 1102 in SEQ ID NO: 1.

Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Chin et al. (On the Preparation and Utilization of Isolated and Purified Oligonucleotides March 9, 2002). Chin et al teach listings of oligonucleotide sequences consisting of all sequences of 8 to 12 nucleotides that have between 40 and 60 percent G+C content and are free of homopolymeric runs of 4 or more bases and directly or inversely repeated regions of 4 or more bases. Chin et al disclose a 10-mer oligonucleotide sequence - 5' CCAGTGTGTC 3' - anticipating part of the embodiments of the generic claim (claim 1) which includes- at least a 10-mer sequence in SEQ ID NO: 1 comprising a G to A variant at a position corresponding to position 1509.

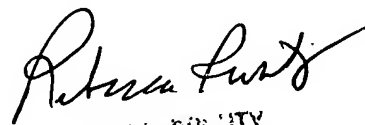
Claims 11 and 12 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagne H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kagne H. Gebreyesus PhD.


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